

**Miracle-Ear®**

Hearing Systems by Bausch & Lomb

David D. Riccardi  
A & M Hearing, Inc.  
DBA Miracle-Ear®

Monday, October 16, 2000

**Honorable Donna E. Shalala**  
Secretary of Health & Human Services  
200 Independence Avenue S.W. Room 615F  
Washington, DC 20201

Dear Secretary Shalala,

Good Morning. I am a small business owner in the state of Pennsylvania providing hearing healthcare services to the hearing impaired in Erie, Crawford, Venango, and Mercer counties. We maintain five offices, six service centers, and employ fifteen people. I am proud to say that we have been able to provide employment for Pennsylvania residents and help the areas hearing impaired for over forty-three years. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing healthcare and reduce access to the state hearing healthcare providers. As a long time businessman in Pennsylvania, I implore you to please take the time to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing healthcare providers, as required by the **SMALL BUSINESS REGULATORY, ENFORCEMENT FAIRNESS ACT (SBREFA)**.

Hearing healthcare providers like myself have been working with the FDA since the early 90's to streamline the current FDA hearing aid regulations. Now, just weeks before the election of Administration, the FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like myself from the marketplace. FDA repeatedly favors allowing each state to determine the conditions for dispensing hearing aids. This will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing healthcare without any medical or health policy justifications.

As you may have seen, the AARP recently published a CONSUMER GUIDE to HEARING AIDS, which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20% of those that need a hearing aid have one". Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

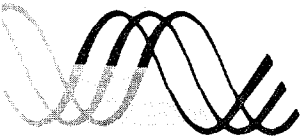
I appreciate your time to consider my views on this critical issue and would be delighted to be of any assistance in this matter.

Please don't let the FDA publish its proposed hearing aid rule.

Sincerely yours,

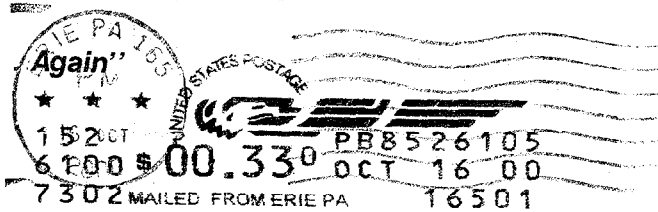
David D. Riccardi  
President 93N 0372

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"We're Helping People Listen To Life . . .



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